

# United States District Court, Northern District of Illinois

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| Name of Assigned Judge or Magistrate Judge | Charles P. Kocoras                 | Sitting Judge if Other than Assigned Judge |            |
| CASE NUMBER                                | 00 C 1475                          | DATE                                       | 12/13/2000 |
| CASE TITLE                                 | Pfizer, Inc. vs. Novopharm Limited |  |            |

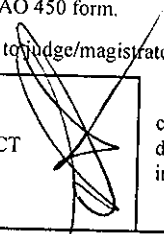
[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

## MOTION:

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## DOCKET ENTRY:

- (1) ☐ Filed motion of [ use listing in "Motion" box above.]
- (2) ☐ Brief in support of motion due \_\_\_\_\_.
- (3) ☐ Answer brief to motion due \_\_\_\_\_. Reply to answer brief due \_\_\_\_\_.
- (4) ☐ Ruling/Hearing on \_\_\_\_\_ set for \_\_\_\_\_ at \_\_\_\_\_.
- (5) ☐ Status hearing[held/continued to] [set for/re-set for] on \_\_\_\_\_ set for \_\_\_\_\_ at \_\_\_\_\_.
- (6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on \_\_\_\_\_ set for \_\_\_\_\_ at \_\_\_\_\_.
- (7) ☐ Trial[set for/re-set for] on \_\_\_\_\_ at \_\_\_\_\_.
- (8) ☐ [Bench/Jury trial] [Hearing] held/continued to \_\_\_\_\_ at \_\_\_\_\_.
- (9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]  
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).
- (10) ☒ [Other docket entry] Ruling held. **ENTER MEMORANDUM OPINION:** Novopharm's motion (Docs 17-1 & 17-2) for a separate trial and stay of discovery on the issue of willful infringement is granted. We order that issues relating to damages, including the issue of willful infringement, be tried separately from and after trial of the liability issues. Discovery relating solely to opinions and advise of counsel bearing on willfulness are stayed pending a determination on the issue of liability.
- (11) ☒ [For further detail see order attached to the original minute order.]

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| <input type="checkbox"/> No notices required, advised in open court.<br><input type="checkbox"/> No notices required.<br><input type="checkbox"/> Notices mailed by judge's staff.<br><input type="checkbox"/> Notified counsel by telephone.<br><input checked="" type="checkbox"/> Docketing to mail notices.<br><input type="checkbox"/> Mail AO 450 form.<br><input type="checkbox"/> Copy to judge/magistrate judge. | SCT<br><br>courtroom deputy's initials | CO-7<br>FILED FOR DOCKETING<br>00 DEC 13 PM 3:48 | number of notices         | Document Number<br>23 |
|   |   |  | DEC 14 2000               |                       |
|   |   |  | date docketed             |                       |
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|   |   |  | date mailed notice        |                       |
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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

PFIZER INC. and PFIZER  
TECHNOLOGIES LIMITED,

Plaintiffs,

vs.

NOVOPHARM LIMITED,

Defendant.

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00 C 1475

**MEMORANDUM OPINION**

CHARLES P. KOCORAS, District Judge:

This matter is before the court on the motion of Defendant Novopharm Limited for a separate trial and stay of discovery on the issue of willful infringement. For the reasons set forth below, we grant Defendant's motion.

**BACKGROUND**

Plaintiffs Pfizer, Inc. and Pfizer Technologies Limited (collectively, "Pfizer") are the owner and beneficial owner, respectively, of U.S. Patent No. 4,404,216 (the "'216 patent") for an antifungal compound known as fluconazole. Pfizer markets fluconazole under the trade name Diflucan®. In January of 2000, Defendant Novopharm Limited ("Novopharm") submitted an Abbreviated New Drug Application (the "ANDA") to the U.S. Food and Drug Administration in an effort to obtain approval to engage in the commercial manufacture, use or sale of fluconazole tablets prior to the expiration of the '216 patent. The ANDA included

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a Paragraph IV Certification containing Novopharm's opinion that Pfizer's '216 patent was invalid (the "ANDA"). See 1 U.S.C. § 355(j)(2)(A)(vii)(IV).

Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Novopharm's then counsel, Robert F. Green of Leydig, Voit and Mayer, Ltd., provided Pfizer with written notice of the ANDA on January 28, 2000. As required by statute, the notice contained a detailed statement of the factual and legal bases for Novopharm's claim that the '216 patent was invalid. In particular, Novopharm claimed that the '216 patent was "invalid as anticipated under 35 U.S.C. § 102(e) in view of the disclosure set forth in U.S. Patent 4,416,682" (the "'682 patent"). Section 102(e) provides that an applicant may not receive a patent for an invention that has been described in an application for patent by another filed before the invention by the applicant for patent. The January 28 notice letter set forth in detail Novopharm's belief that the "disclosure of the limited genus of compounds in the '682 patent, when considered in light of the totality of the circumstances, identifies the claimed species (i.e. fluconazole) covered by claim 1 of the '216 patent with sufficient specificity to constitute a description within the meaning of 35 U.S.C. § 102(e)."

Pfizer maintains that the '216 patent is valid. It therefore filed this infringement action pursuant to 35 U.S.C. 271(e),<sup>1</sup> alleging that Novopharm wilfully infringed the '216 patent by filing the ANDA without a reasonable belief that the '216 patent was invalid.

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<sup>1</sup> The submission of a Paragraph IV certification with respect to a drug for which the existing patent is valid is deemed an act of infringement. 35 U.S.C. § 271(e).

Novopharm has moved for separate trials on the issues of liability and willfulness, and for a stay of discovery with respect to the latter.

## **DISCUSSION**

Rule 42(b) of the Federal Rules of Civil Procedure authorizes the Court to order a separate trial of any claim or issue in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy. Bifurcation in patent cases, as in others, is the exception and not the rule. Real v. Bunn-O-Matic Corp., 195 F.R.D. 618, 620 (N.D. Ill 2000) (citing cases). The decision to order separate trials is made on a case-by-case basis and is committed to the broad discretion of the trial court. United States Gypsum Co. v. National Gypsum Co., 1994 WL 74989, at \*1 (N.D. Ill. March 10, 1994).

### **I. Quantum dilemma prejudice**

The Federal Circuit has advised courts in patent cases to carefully consider bifurcation of liability and willfulness issues to avoid what has become known as a Quantum dilemma. In Quantum Corp. v. Tandon Corp., 940 F.2d 642, 643-44 (Fed. Cir. 1991), the court explained that, in willful infringement cases, the accused infringer may be presented with a Hobson's choice between waiving the attorney-client privilege in order to mount an "advice of counsel" defense and maintaining the privilege with the risk that it will be found to be a willful infringer if liability is found. The court therefore advised:

Trial courts thus should give serious consideration to a separate trial on willfulness whenever the particular attorney-client communications, once

inspected by the court in camera, reveal that the defendant is indeed confronted with this dilemma. While our court has recognized that refusal of a separate trial will not require reversal in every case involving attorney client communication bearing on willfulness, we have suggested the advisability of separate trials in appropriate cases. Id. at 644 (citing Fromson v. Western Litho Plate & Supply Co., 853 F.2d 1568, 1572 (Fed. Cir. 1988)).

Novopharm does not contend that it is presently faced with a Quantum dilemma, and it has presented no attorney opinion documents for in camera review. Rather, Novopharm argues that the mere potential for the existence of a Quantum dilemma is sufficient to demonstrate that bifurcation is necessary to avoid prejudice to Novopharm. In support of its argument, Novopharm cites the opinion in Princeton Biochemicals, Inc. v. Beckman Instruments, Inc., 180 F.R.D. 254, 45 U.S.P.Q.2d 1757 (D.N.J. 1997). In Princeton, the district court for the District of New Jersey ordered separate trials on the issues of liability and damages without reaching the question of whether there existed a Quantum dilemma. Id. at 260. Far from holding that no such determination is necessary to evaluate Quantum-related claims of prejudice, however, the court explicitly recognized that “a court faced with this issue *must make an in camera review* of the written opinion in question in order to determine whether disclosure would, in fact, prejudice the alleged infringing party on the issue of liability.” Id. (citing Neorx Corp. v. Immunomedics, Inc., 28 U.S.P.Q.2d 1395, 1993 WL 592531 (D.N.J. 1993) (emphasis added)). Nevertheless, the court determined that such an inquiry was unnecessary in the case before it because it had already found there to be no significant overlap between the issues of liability and willfulness. It therefore thought

bifurcation appropriate regardless of whether the defendant was faced with a Quantum dilemma.

Accordingly, and in light of the Quantum court's admonition that "the court's inspecting the documents in camera before ruling on the motions to compel production and defer trial on willfulness was certainly proper and deserves emulation," we hold that Novopharm cannot establish that bifurcation is necessary to avoid Quantum-type prejudice without first demonstrating that it is actually faced with a Quantum dilemma. This it has chosen not to do. Nevertheless, bifurcation may still be advisable, since Novopharm argues that it would be more convenient, expeditious, or economical than trying the issues of liability and willfulness together.

## **II. Judicial economy**

Novopharm argues that separating the issues of liability and willfulness for purposes of discovery and trial would further the interests of convenience, expedition, or economy. Bifurcation could be highly efficient, in that a verdict of no liability for infringement would render discovery and trial on the willfulness issue unnecessary. A verdict in favor of Pfizer following the liability stage of a bifurcated trial, on the other hand, would require us to reopen discovery and, most likely, hold a second trial, with a new jury, on the issue of willfulness. Bifurcation thus carries both the potential for judicial economy and the risk of unnecessary duplication and delay. Where we strike the balance between these two possibilities depends largely on the extent to which the evidence supporting Pfizer's liability and willfulness claims overlaps.

Novopharm argues that there is no significant overlap between the facts necessary to establish infringement and willfulness. Because liability is a function of the objective validity of the '216 patent and willfulness is a function of Novopharm's subjective intent and belief, Novopharm argues, the evidence presented in support of each claim will be different. Pfizer, on the other hand, argues that the facts in support of its infringement and willfulness claims are inextricably intertwined such that bifurcation will result in duplicative proceedings. In particular, Pfizer argues that the validity of its '216 patent in view of the disclosure of prior art set forth in the '682 patent is central to both its infringement and willfulness claims, and that both of those claims will turn on evidence of "what is taught by the '682 patent." Pfizer represents that it intends to support both its liability and willfulness cases with evidence of Novopharm's "shifting positions" on that issue.

The parties agree that, currently, the only issue for the jury on Pfizer's liability claim is whether the '216 patent is valid. If not, Novopharm cannot be held liable for infringing it, willfully or otherwise. If the '216 patent is valid, on the other hand, Novopharm is automatically liable for infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Once Novopharm's liability is established, Pfizer may proceed to demonstrate willful infringement by showing with clear and convincing evidence that Novopharm acted without regard for the patent and without a reasonable basis for believing that it had a right to act in an infringing fashion. SmithKline Beecham Corp. v. Apotex Corp., 2000 WL 983937, at \*3 (N.D. Ill. July 17, 2000) (citing cases); Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc.,

2000 WL 1644602 (Fed. Cir. Nov. 3, 2000) (upholding finding of willful infringement under § 271(e) for filing of unjustified paragraph IV ANDA).

According to Pfizer, Novopharm has taken different positions at different times on the question of whether, and why, the '216 patent was invalid in view of disclosures in the '682 patent. This evidence is clearly relevant to the issue of willfulness, since it suggests Novopharm's lack of a reasonable basis for contending in the course of this litigation that the '216 patent is invalid. We are unconvinced, however, that Novopharm's prior subjective interpretation of the '216 patent is relevant to the question of whether that patent is objectively valid. As discussed above, this objective validity is the only issue for the jury on Pfizer's infringement claim. We therefore reject the argument that evidentiary overlap in this area dictates denial of the motion to bifurcate. Cf. Princeton Biochemicals, 180 F.R.D. at 258 and fn. 3 ("plaintiff's argument that willful infringement substantially overlaps liability and damages issues is unconvincing," since the two are distinct causes of action with different elements).

Pfizer next argues that what it refers to as the international scope of the case supports trying the liability and willfulness issues together. It emphasizes that the inventors of the '216 and '682 patents reside in the U.K. and that the research with respect to the discovery and testing of fluconazole was conducted in the U.K. and France. Novopharm's headquarters, and its parent company's headquarters, are similarly located outside the United States. Pfizer contends that it would be unfair and inefficient to conduct two independent



rounds of discovery in these locations and to require witnesses from these foreign locations to travel to the United States twice for separate trials.

While Pfizer's argument is, in theory, a solid one, it has failed to show that the testimony of any particular witness would be needed at both the liability and willfulness trials. For example, while the patent inventors will be important witnesses on the issue of liability, it is unclear what relevance their testimony would have on the question of Novopharm's subjective intent in filing the ANDA. Similarly, Pfizer fails to explain why witnesses from Novopharm's foreign locations would be needed in both trials. Novopharm, on the other hand, warrants that the likely witnesses on willfulness – Novopharm employees who reportedly relied on the opinions of counsel – lack factual evidence relating to the invalidity of the '216 patent and will not be called by Novopharm to testify on that subject. It further argues that efficiency and fairness are served by postponing the depositions of these international witnesses until it is clear that they are necessary, i.e. after a determination of liability is made. In the absence of a demonstrated overlap between the witnesses and proof needed in each of the two proposed trials, Novopharm has the better position.

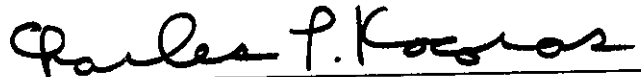
Finally, Pfizer argues that bifurcation is unnecessary to simplify the case – an uncomplicated one by patent standards – for the jury. We agree, but find bifurcation appropriate for the other reasons discussed above.

In sum, based on the likely evidence and arguments as they have been presented to us, we find little, if any, evidentiary overlap between the issues of liability and willfulness. Accordingly, and because a finding of no liability would obviate the need for discovery and

trial on the willfulness issue, we strike the balance of conveniences in favor of bifurcation. Moreover, as discussed above, the risk of duplication and delay is minimal. Any prejudice to Pfizer resulting from bifurcation is therefore outweighed by the likelihood that Novopharm will, at some point, face a Quantum dilemma. We therefore conclude that bifurcation of the liability and willfulness issues for the purposes of trial and discovery is warranted.

### CONCLUSION

For the foregoing reasons, Novopharm's motion is granted. We order that issues relating to damages, including the issue of willful infringement, be tried separately from and after trial of the liability issues. Discovery relating solely to opinions and advice of counsel bearing on willfulness are stayed pending a determination on the issue of liability.



Charles P. Kocoras  
United States District Judge

Dated: December 13, 2000